## REMARKS

Claims 1, 2, 5-17, and 19-21 were examined and rejected. Claims 1, 19, and 21 have been amended. Claims 22-42 have been canceled. Re-examination and reconsideration of the pending claims 1-21 are respectfully requested.

### Amendments to Specification/Abstract

Applicants have amended the specification to provide U.S. Patent Application Nos. that were previously referred to by Attorney Docket Nos. as this information is now available. No new matter has been added thereby.

Applicants have also amended the abstract to provide more general terminology for the legal term "means" as requested by the Examiner. This amendment is supported in the originally filed application on page 5, lines 16-29. As such, no new matter has been introduced.

### Formal Matters

Claims 19 and 21 have been amended to now depend from elected base claims, as requested by the Examiner.

### Restriction Requirement

Claim 22-42 have been canceled without prejudice pursuant to a restriction requirement. Applicants reserve the right to pursue patent protection for these inventions in a subsequently filed application. Dependent claims 3, 4, and 18 stand withdrawn as being drawn to a non-elected species. Currently, independent claim 1 is generic.

### Substantive Claim Rejections under 35 U.S.C. § 102(b)

Claims 1, 5, and 8-10 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,800,392 issued to Racchini. Claims 1, 5, and 8-10 have also been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,286,254 issued to Shapland et al. Such rejections are respectfully traversed as follows.

Claim 1 recites a combined radiation and radiosensitizer delivery catheter for inhibiting hyperplasia comprising a catheter body, an ionizing radiation source for applying a radiation dose to a body lumen, and means for releasing a radiosensitizer to the body lumen. In particular, the combined radiation and radiosensitizer delivery catheter inhibit hyperplasia.

Such a combined radiation and radiosensitizer delivery catheter for inhibiting hyperplasia has not been reasonably disclosed or suggested by the cited art references.

As the Examiner certainly knows and appreciates, a single cited art reference must teach each and every element of the claim to establish anticipation under 35 U.S.C. § 102. M.P.E.P. § 2131. The Court of Appeals for the Federal Circuit has held that, "the identical invention must be shown in as complete detail as is contained in the .... claims." *Richardson v. Suzuki Motor Co.*, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). The Racchini and Shapland et al. references fail to teach or suggest a radiation source for applying a radiation dose to a body lumen, much less a combined radiation and radiosensitizer delivery catheter to inhibit hyperplasia.

The Examiner asserts Racchini and Shapland et al. disclose an ionizing radiation source 28. Office Action dated January 15, 2003, pages 2-3. However, a closer review of these references reveals that Racchini with respect to Fig. 5 and Shapland et al. with respect to Fig. 6 instead teach iontophoresis means 28 to transport a drug across a balloon surface and into contact with a vessel wall. Specifically, a first electrode 28 is located on a catheter body 11 and connected to a power supply 30 by a lead 29. A second electrode 31 is located on a body surface and is connected to the power supply 30 by a lead 33. The power supply 30 provides an electric current between the first and second electrodes. During operation, a balloon 12, 26 is positioned within a vessel 15 and the balloon interior 13, 27 inflated. The power supply 30 is then activated thereby creating a current between the first and second electrodes which passes through the balloon wall 26. This current drives or drags the agent from the balloon interior across the wall and into contact with the surrounding vessel wall. See Racchini col. 7, lines 44-60; col. 10, lines 51-67; Shapland et al. col. 9, line 44 through col. 10, line 17. Both of these references are limited to solely drug delivery therapy to inhibit restenosis after PTCA via electrode phoresis transport means. Applicants fail to remotely identify any radiation modalities in Racchini or Shapland et al.

Moreover, Applicants note that the cited art references further fail to teach means for releasing a radiosensitizer to the body lumen as currently claimed by claim 1. "Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. . . . There must be no difference between the claimed

invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." *Scripps Clinic & Research Found. v. Genentech Inc.,* 18 USPQ 2d 1001, 1010 (Fed. Cir. 1991). Applicants request, if the present rejection is maintained, that the Examiner show or explain where the cited art references, alone or in combination, describe or suggest a combined radiation source that applies a radiation dose and radiosensitizer delivery catheter to inhibit hyperplasia.

The present invention advantageously provides a combined radiation therapy and radiosensitizer delivery to inhibit hyperplasia. In particular, such a combination may reduce and/or inhibit hyperplasia with increased efficiency. For example, in some instances the radiation dosage may provide an immediate inhibition while the radiosensitizer may provide a prolonged inhibition. Furthermore, a combined balance of both therapies allows for reduced dose concentrations of radiation and/or radiosensitizers in the body lumen, as compared to relying on a single therapy. Prior to the new teachings included for the first time in the present application, no cited art record of reference (including Racchini or Shapland et al., alone or in combination) has been shown to remotely teach or suggest this significant and distinct structure of a combined radiation source that applies a radiation dose and radiosensitizer delivery catheter to inhibit hyperplasia as recited in claim 1. As such, claim 1 (and dependent claims 2-21) are in condition for allowance.

Substantive Claim Rejections under 35 U.S.C. § 103(a).

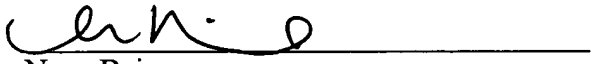
Dependent claims 2, 19, 20, and 21 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Shapland et al. or Racchini in view of U.S. Patent 6,390,967 issued to Forman et al. Applicants note that the Forman et al. reference qualifies as prior art only under 35 U.S.C. 102(e) as it was filed on September 14, 2000 and issued on May 21, 2002 and the present application was filed on May 7, 2001. Moreover, the Forman et al. patent and the present invention were, at the time the present invention was made, subject to an obligation of assignment to a common assignee, Xoft microTube, Inc. Hence, the present rejection can not preclude patentability under 35 U.S.C. § 103(c) and as such should be removed. Hence, dependent claims 2, 19, 20, and 21 are further in condition for allowance in addition to the reasons given above.

## CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,



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